NDA 20-457/S002

Bristol-Myers Squibb Pharmaceutical Research Institute
Attention: Susan Behling
Regulatory Affairs, Associate Director
5 Research Parkway - P.O. Box 5100
Wallingford, CT 06492-7660

Dear Ms. Behling:

Please refer to your supplemental new drug application dated February 28, 1997, received March 3, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Etopophos (etoposide phosphate).

This "Changes Being Effected" supplemental new drug application provides for revisions in the ADVERSE REACTIONS and WARNINGS sections re: myelosuppression, interstitial pneumonitis/pulmonary fibrosis, and seizures.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted February 28, 1997). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Debra Vause, B.S.N., Regulatory Project Manager, at (301) 594-5724.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Richard Pazdur

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